In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-0817V UNPUBLISHED

JUDY BELL,

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: September 8, 2021

Special Processing Unit (SPU); Findings of Fact; Onset; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Jeffrey S. Pop, Jeffrey S. Pop & Associates, Beverly Hills, CA, for Petitioner.

Ronalda Elnetta Kosh, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On June 3, 2019, Judy Bell filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered left shoulder injuries related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine received on October 10, 2017. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find onset of Petitioner's shoulder pain occurred within the Table period (here, immediately after vaccination).

I. Relevant Procedural History

Following the initial status conference, Respondent was directed to file a status report indicating his position in the case. Scheduling Order, issued Aug. 9, 2019 (ECF No. 10). On May 4, 2020, when the case had been pending for eleven months, Respondent filed a status report stating that the case had not been reviewed and would not undergo review for at least an additional 90 days. Respondent's Status Report, filed May 4, 2020 (ECF No. 18). Respondent was then directed to file a status report providing counsel's informal assessment of the case. Scheduling Order, issued May 6, 2020 (ECF No. 19). Respondent did so on July 7, 2020, identifying no specific issues with the case or record filings (ECF No. 20).

Respondent later, however, expressed the intent to defend the claim, and on November 2, 2020, filed his Rule 4(c) Report asserting that the case was not appropriate for compensation. Rule 4(c) Report, filed Nov. 2, 2020 (ECF No. 22). Respondent's primary contention was that it was not clear that the onset of Petitioner's shoulder pain began within 48 hours of vaccination.³ *Id.* at *6. I thereafter directed Petitioner to file a motion for a fact ruling concerning onset, along with any additional evidence she wished to provide. Scheduling Order, issued Dec. 2, 2020 (ECF No. 23). Petitioner filed her motion for a fact ruling, along with additional evidence, on February 8, 2021 (ECF Nos. 24-25). Respondent filed a response on March 10, 2021 (ECF No. 26), and Petitioner replied on March 17, 2021 (ECF No. 27). The issue of the onset of Petitioner's shoulder pain is now ripe for resolution.

II. Issue

At issue is whether Petitioner's first symptom or manifestation of onset (specifically pain) occurred within 48 hours after vaccine administration as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(a) XIV.B. (2017) (influenza vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

³ Onset had not been identified in counsel's informal assessment, but was raised for the first time in the Rule 4 Report – an unexpected development, particularly in light of the robust record evidence supporting a finding of onset within 48 hours and the relatively weak concerns raised by Respondent to the contrary.

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19. And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569

F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Parties' Positions

a. Petitioner's Arguments

Petitioner asserts that her pain started directly after receiving the flu vaccine on October 10, 2017. Pet. Mot. at *6. She states that when she sought care from numerous health care providers, she consistently linked her shoulder pain to the October 10 flu vaccine. *Id.* at *8. In particular, after receiving the flu vaccine, she noticed a hard knot at the injection site. *Id.* at *10 (*citing* Ex. 1 at ¶ 6 and Ex. 15 at ¶¶ 4-6). She adds that four separate witnesses recall her complaining of left shoulder pain after receiving the vaccine. *Id.* Petitioner argues that a preponderance of the evidence indicates that she suffered immediate pain after the October 10, 2017 flu vaccine. *Id.* at 12.

In addition, Petitioner notes that three different healthcare providers documented that the onset of her injury as having occurred within 48 hours of vaccination. Petitioner's Reply ("Reply") at *2. And other instances of "silence" in medical records does not negate her claim. *Id.* She emphasizes that she did not have any intervening medical visits between receiving the vaccine and reporting her symptoms on January 25, 2018. *Id.* at *2-3. With respect to her physician's phone records, she asserts that their failure to memorialize her shoulder symptoms does not negate her assertion that her symptoms began within 48 hours. *Id.* at *3. She argues that when her declarations are evaluated in

concert with the medical records, the record supports a finding that her shoulder pain began within 48 hours of vaccine administration. *Id.* Petitioner adds that she still has a knot at the injection site and has filed a photograph thereof as further proof of onset. Reply at *3-4.

b. Respondent's Arguments

Respondent notes that Petitioner did not seek care until 108 days after vaccination. Respondent's Response to Motion ("Response") at *2. Indeed, Petitioner called her doctor's office on October 19, 2017, nine days after vaccination, to request additional insulin needles, but did not report shoulder pain. Response at *14. And although there is record support that she called her doctor's office several times in the interim, the records of these calls do not document shoulder pain or discomfort. *Id.* at n.1.

Such records, Respondent maintains, are entitled to reliability presumptions. *Cucuras*, 993 F.2d at 1528; Response at *13-14. They deserve more weight than her own claims - which cannot alone, unsubstantiated by medical records or medical opinion, be the basis for an entitlement determination. *Id.* at *10 (*citing* Vaccine Act § 13(a)). And here, this kind of evidence is itself problematic. Thus, although Petitioner has provided declarations indicating that she complained of left shoulder pain on the day of, or in the days following, vaccination, she did not report any of these complaints to medical providers despite numerous opportunities to do so. Response at *14. Petitioner therefore cannot meet this Table requirement.

V. Finding of Fact

I make the following findings after a complete review of the record, which includes all medical records, declarations, Respondent's Rule 4 report, and additional evidence filed:

- The October 10, 2017 vaccine administration record establishes that Petitioner received a flu vaccine in her left deltoid on that date. Ex. 2 at 1.
- Family First telephone records, establishing that Petitioner called eight times between October 19 and December 22, 2017, for prescription refills and concerning the results of a sleep study and sleep apnea.⁴ Ex. 10 at 1-11. These records are silent on shoulder or arm complaints.

⁴ There was also a telephone encounter on October 16, 2017, which the record indicates was initiated from Family First to inform Petitioner of abnormal labwork results, and to recommend medication in response. Ex. 10 at 12.

- The record of Petitioner's January 25, 2018 appointment with Nurse Practitioner ("NP") Rachael Sapp, at which Petitioner reported pain in her left arm where she had her flu shot, radiating up to her shoulder. Ex. 3 at 11. Petitioner reported that the pain made it difficult to hold a coffee cup. *Id.* On examination, the range of motion in Petitioner's left shoulder was found to be reduced by 50% due to pain. *Id.* Petitioner was assessed with a skin lesion in her left deltoid. *Id.* at 10. She was given pain medication and an ultrasound was ordered. *Id.*
- The record of Petitioner's February 7, 2018 left shoulder ultrasound. Ex. 4 at 60-61. The ultrasound was ordered due to a history of pain and a shot in Petitioner's left shoulder. *Id.* at 60. The test revealed an area that "most likely" represented a fluid collection. *Id.* The findings were interpreted as "suggestive of a possible subcutaneous contusion/resolving hematoma." *Id.*
- The record of Petitioner's April 26, 2018 appointment with NP Sapp, at which Petitioner reported persistent left arm pain since her flu shot, in addition to left arm weakness. Ex. 3 at 6. Petitioner reported that she experienced increased pain at work as a certified nurse assistant ("CNA") moving patients. Id. at 6. On examination, Petitioner was found to exhibit tenderness in the mid-deltoid area, and was directed to continue taking pain medication. Id. at 5-6.
- The record of Petitioner's July 11, 2018 appointment with orthopedic physician's assistant ("PA") Danny Eagle. Ex. 4 at 49. PA Eagle documented that Petitioner's chief complaint was left shoulder pain that began at the injection site after Petitioner received a flu shot the year before. Id. at 49-50. Petitioner reported, "[a]fter the injection she noticed a knot at the injection site. Her LEFT arm and shoulder has hurt since then." Id. at 50. At worst, the pain was 9-10 on a scale of 0-10, and the pain was aggravated by lifting, carrying, pushing/pulling, and range of motion. Id. On examination, Petitioner was found to have reduced range of motion and an asymmetric left shoulder hike. Id. at 51. PA Eagle's ability to perform special tests was "limited due to her inability to elevate the arm and noted adhesion." Id. PA Eagle assessed Petitioner with adhesive capsulitis. Id. at 52. He administered a steroid injection and referred Petitioner for physical therapy. Id. at 51-52.
- The record of Petitioner's July 12, 2018 physical therapy evaluation, indicating that her left shoulder pain resulted from a flu shot and had

persisted for nine months. Ex. 6 at 4. Petitioner reported being concerned that the pain remained severe and was not going away. *Id.* On examination, severe tender taut fibers were observed over Petitioner's left shoulder, left anterior shoulder, and left supraspinatus tendon. *Id.* at 3. Apley's scratch test was positive on the left side. *Id.* Petitioner's range of motion was reduced in all planes and painful. *Id.* at 2-3.

- The record of Petitioner's August 1, 2018 appointment with NP Sapp, noting that Petitioner reported that she had seen an orthopedist who stated that her left shoulder pain was related to her flu shot. Ex. 3 at 2-3.
- The record of Petitioner's January 25, 2019 appointment with Dr. Saira Nasser, indicating that Petitioner reported left shoulder pain caused by a flu shot the year before. Ex. 5 at 1. On examination, Dr. Nasser found that Petitioner's left shoulder range of motion was reduced and that she could not raise her arm above her shoulder. *Id.* at 2. Petitioner was given a prescription for meloxicam and advised to continue taking Flexeril as needed. *Id.* at 3.
- Petitioner's declaration averring that she experienced immediate pain after receiving her flu shot. Ex. 1 at ¶ 6. She stated that she developed a hard knot at the injection site, and within a few days could not lift her arm. *Id.* She added that she called her doctor's office both within a week of the flu shot and over the next two months, and was told to ice her shoulder and the pain would go away. *Id.* at ¶¶ 6-7; Ex. 15 at ¶¶ 10-11. Petitioner explained that she did not initially go in to see her doctor because she was repeatedly told on the phone that with icing the pain would go away. Ex. 1 at ¶ 7. Petitioner reported that she works as a CNA and her injury had impaired her ability to move patients. *Id.* at ¶ 17. Petitioner added that her mother came with her to the appointment where she received the flu shot, and afterward they ate together. Ex. 15 at ¶¶ 3, 5. Petitioner stated that she told her mother that her arm still hurt. *Id.*
- A declaration from Petitioner's mother, Shirley Ramirez. Ex. 11. Ms. Ramirez averred that while eating just after Petitioner received the flu shot, Petitioner reported that her shoulder was hurting. *Id.* at ¶ 9. She reported that Petitioner continued to complain of shoulder pain when they got home and the following day. *Id.* at ¶¶ 9-10. Ms. Ramirez averred that her sister Sharon Cash, who is Petitioner's aunt, died on October 11, 2017 and the funeral was held on October 13, 2017. *Id.* at ¶¶ 11-12. Ms. Ramirez reported that Petitioner complained about shoulder pain to another aunt at the

funeral. *Id.* at ¶¶ 11-12. Petitioner submitted Ms. Cash's obituary, indicating that Ms. Cash passed away on October 11, 2017 and her funeral was on October 13, 2017. Ex. 17.

- A declaration from Petitioner's daughter, Hope Bell, who also works as a CNA. Ex. 12 at ¶ 4. Petitioner's daughter averred that in 2017 she lived next door to her mom and saw her daily. Id. at ¶ 6. Ms. Bell averred that the day after her mother's flu shot, her mother complained of pain and soreness in her left shoulder where she received the flu shot. Id. at ¶ 8. Ms. Bell reported that she looked at the injection site and observed that it was red and swollen, with a knot. Id. at ¶ 9.
- Ms. Bell also stated that she advised her mother to call her doctor, and that when her mother did so, the doctor's office stated that the reaction was normal and she should ice her shoulder. Ex. 12 at ¶¶ 10-11. Her mother did ice her shoulder, but that rather than improving, she experienced more pain and limitations within about a week of the flu shot. *Id.* at ¶¶ 12-13. Ms. Bell observed that her mother's ability to lift her arm was limited. *Id.* at ¶ 13. Ms. Bell averred that she began to help her mother with getting dressed and cooking due to her arm pain. *Id.* at ¶¶ 14-15. In particular, on Thanksgiving 2017 Ms. Bell stated that she had to help with the turkey and ham because her mother could not lift or carry them in and out of the oven. *Id.* at ¶ 16.
- An affidavit from Debra Williams, Petitioner's friend and former colleague. Ex. 13. Ms. Williams averred that she spoke to Petitioner a few days after the October 2017 flu shot and was told that Petitioner's shoulder hurt at the injection site. *Id.* at ¶ 10. Petitioner continued to complain of pain over the next month or so, reporting that it was getting worse. *Id.* Ms. Williams averred that Petitioner told her she was icing her shoulder for the pain. *Id.* at ¶ 12. Ms. Williams reported that she visited Petitioner around Christmas of 2017 and noticed that Petitioner could not do certain things due to the pain in her shoulder. *Id.* at ¶ 13. For instance, she could not raise her arm higher than breast height, and needed help carrying a pot. *Id.* at ¶ 14. Ms. Williams reported that during her visit, Petitioner suddenly dropped a coffee mug she was holding in her injured arm. *Id.*
- An affidavit from India Rosebud, another friend and co-worker of Petitioner.
 Ex. 14. Ms. Rosebud averred that she met Petitioner during a work orientation at the end of 2018, and saw her three or four times a week. *Id.* at ¶¶ 6-7. They became friends and shared meals. *Id.* at ¶ 8. As Ms. Rosebud got to know Petitioner, she began noticing Petitioner struggling on

her left side, and needing help to move patients. *Id.* at \P 9. Petitioner requested patients who could do more on their own, so that she would not need to move them. *Id.* at \P 10. Ms. Rosebud recounted an incident at a lunch buffet where Petitioner almost dropped her plate of food. *Id.* at \P 11. Petitioner attributed this to shoulder problems since her flu shot. *Id.* at \P 12.

The above records demonstrate, by a preponderance of the evidence, that Petitioner experienced pain immediately after vaccine administration. Although Petitioner's medical records do not indicate that she sought care until over three months after vaccination, when she *did* seek care she consistently related her pain to her flu shot and reported that she had experienced pain since her flu shot. In these circumstances, the delay in seeking treatment does not undercut Petitioner's claim.

There are some intervening medical records from this period – a number of calls between Petitioner and her health care provider – that do not mention shoulder complaints. Ex. 10 at 1-11. Petitioner asserts, however, that she in fact called her doctor's office a week after the flu shot and over the next two months to complain of shoulder pain and was directed to ice her shoulder, and the pain would go away. Ex. 1 at ¶¶ 6-7; Ex. 15 at ¶¶ 10-11.

Although Respondent reasonably observes that Petitioner had the opportunity to complain of her purported pain but *apparently* did not, Petitioner's declaration testimony to the contrary – both that she *did* complain, and that she was then experiencing pain regardless of what these records indicate - is not rebutted by the phone records' silence on the issue of shoulder pain. Petitioner's calls during this time concerned other health matters unrelated to shoulder pain, and thus the fact that they do not address it does not automatically undercut her assertions. *See Kirby*, 997 F.3d at 1383 ("[w]e see no basis for presuming that medical records are accurate and complete even as to all physical conditions 'the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance' ") (citation omitted). In addition, I credit Petitioner's declaration testimony that she called and was told to ice her shoulder, a contention corroborated by Ms. Bell. Ex. 12 at ¶¶ 10-11.

I do consider Petitioner's three-month delay in seeking care, coupled with her numerous opportunities to bring the pain to the attention of her treaters, to be highly relevant to damages (since it bulwarks the conclusion that her pain was manageable in this timeframe). But it does not prevent the conclusion that she had pain at this time, or that some complaints were disregarded.

Taken together, the larger record supports a finding that Petitioner suffered shoulder pain immediately after vaccine administration. In making this finding, I am not, as Respondent suggests, relying on the claims of Petitioner alone in contravention of Vaccine Act section 13(a). The record contains ample medical record evidence that supports this ruling (even if it admittedly comes later in her treatment course, and is not contemporaneous to the time of vaccine administration). The declarations are consistent with, and thus support, the medical records. The fact that section 13(a) prohibits relying on the claims of a petitioner alone does *not* render a petitioner's declaration and testimony evidence meaningless, as Respondent seems to suggest. *See Kirby*, 997 F.3d at 1383-84 (reinstating special master's determination that a petitioner's testimony, supported by other records, justified finding that symptoms persisted despite medical record silence on such symptoms).

Accordingly, I find there is preponderant evidence to establish that the onset of Petitioner's pain occurred within 48 hours of vaccination. Petitioner's motion for a fact ruling on onset is **GRANTED**.

VI. Scheduling Order

Respondent shall file, by <u>Thursday</u>, <u>October 07</u>, <u>2021</u>, a status report indicating how he intends to proceed in this case in light of the record and this fact ruling. The status report shall indicate whether he is willing to engage in tentative discussions regarding settlement or proffer or remains opposed to negotiating at this time.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master